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Guidance for the Reregistration of Pesticide Products Containing NALED as the Active Ingredient

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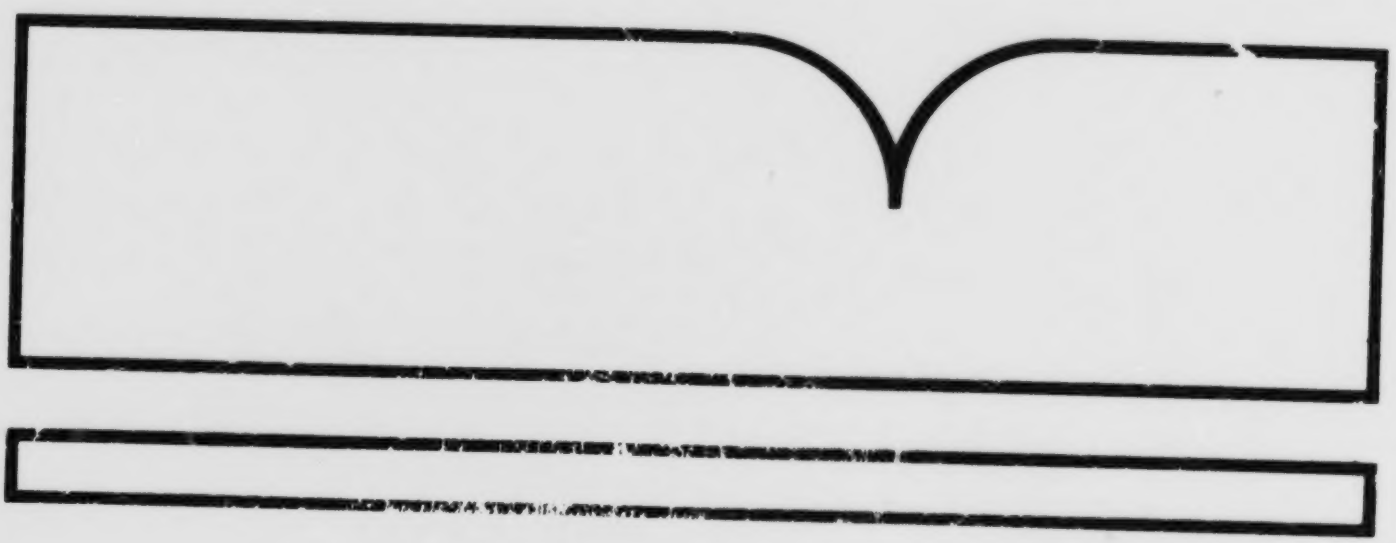

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16. Abstract (Limit: 200 words)

This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS CONTAINING NALED (034401)

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, DC 204060

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Note: Appendices V-1, V-4, and V-6 are not germane to this document and are not included.

Also attached to this document are copies of the letters sent to registrants transmitting the document and notifying them of the studies required.

I. INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(g), as amended in 1978, directs the Environmental Protection Agency (EPA) to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute that product in commerce must apply for reregistration.

This guidance document sets forth certain of the requirements for registration and reregistration of all manufacturing-use products (MPs) containing the subject chemical as the sole active ingredient. These requirements include: that certain scientific data be submitted and that certain standards of toxicity, composition, labeling, and packaging be met. Registrants of MPs are referred to all Sections and Tables for specific information regarding their responsibilities under this guidance document.

This guidance document also sets forth the data requirements for those end-use products which contain the subject active ingredient and for which the source of that active ingredient is (1) not registered with EPA or (2) produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm, or (3) both (1) and (2). Registrants of such end-use products can exempt themselves from these requirements if they change their source of supply to a registered source, provided the source (i.e., registered active ingredient product) is obtained from a firm that does not share ownership in common with the registrant's firm. (If the end-use product registrant decides to switch sources, a new confidential statement of formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this guidance document.) Registrants of affected end-use products are referred to only Sections II, III, and VI and Table A for specific information regarding their responsibilities under this guidance document.

It should be noted that end-use products containing the subject active ingredient will not be reregistered at this time. Any necessary labeling changes will be implemented under the Agency's Label Improvement Program at a future time.

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if the registrant fails to comply with the requirements set forth in this guidance document and with the requirements contained in subsequent information from EPA about compliance with certain data support requirements.

This guidance document has been prepared to provide registrants with specific information on how they may reregister their manufacturing-use products or maintain their end-use products' registration. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined.

Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

This guidance document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

II REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This Registration Standard describes the regulatory position of the Environmental Protection Agency (the Agency) on registered manufacturing-use products (MPs) containing the insecticide-acaricide, naled. The Agency's position is based on a consideration of available data for all currently registered uses and registered MPs with naled as the sole active ingredient. This position is based on a number of considerations. The Standard considers labeling requirements, tolerances, "Special Local Need" registrations authorized by FIFRA Section 24(c), as well as Federal registration granted or pending under FIFRA Section 3. Finally, the Agency sets forth the data requirements that must be met to register products covered by this document.

This Standard only addresses registration requirements for current or substantially similar future MPs and their intermediaries. Naled MPs that differ appreciably from those described here may require amendments to the Standard.

B. CHEMICAL DESCRIPTION AND USE PROFILE

In the United States, naled is the American National Standards Institute (ANSI) approved common name for a halogenated organophosphorus insecticide-acaricide manufactured by the Chevron Chemical Company. The chemical name is 1,2-dibromo-2,2-dichloroethyl dimethyl phosphate. Other names include

Dibrom®, Ortho-Dibrom®, RE 4355, and phosphoric acid 1,2-dibrom-2,2-dichloroethyl dimethyl ester. The Chemical Abstracts Registry (CAS) number for naled is 300-76-5, and the EPA chemical code number is 034401.

Manufacturing-use naled is a light, straw-colored oily liquid with a slightly pungent odor. The pure compound is a white low melting point solid. The boiling point for pure naled is 120°C at 0.5 mm Hg and the vapor pressure is 2×10^{-4} mm Hg at 20°C. The empirical formula is $C_4H_7O_4PBr_2Cl_2$ and the molecular weight is 381. Naled has a limited solubility in aliphatic solvents; is highly soluble in oxygenated solvents such as ketones and alcohols; and a low solubility in water.

There are currently three registered manufacturing-use products consisting of the technical grade of naled (90%), and fifteen (15) registered end-use products containing naled as the sole active ingredient. There are also currently eighty-five (85) products containing naled in combination with other pesticides. In addition, there are twenty-six (26) FIFRA Section 24(c) "Special Local Need" registraions.

Naled is a non-systemic insecticide-acaricide registered for use on field, vegetable, and orchard crops; livestock and poultry, and their surroundings; greenhouses; forest and wasteland; agricultural, domestic, medical, and commercial establishments; and urban and rural outdoor areas

(mosquito control). The major use sites are: fruit, nut, vegetable, and field crops; adult mosquito control; pets, and livestock.

Naled is formulated into dusts (4% and 6%), impregnated materials (10%-25%), emulsifiable concentrates (2-7.2 lb/gal and 6%-26%), soluble concentrates/liquid (2.35-14 lb/gal,and 11.4% and 20%), and ready-to-use liquids (1.26-12.6 lb/gal and 1%-15%). Naled is applied on agricultural crops by using aircraft and ground equipment including mist blowers and foggers.

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on naled, the Agency had made the following determinations:

1. Manufacturing-use products containing naled as the sole active ingredient may be registered for sale, distribution, and reformulation into end-use products, for use, subject to the terms and conditions specified in this Standard.

2. Registrants must provide or agree to develop additional data, as specified in TABLE A and TABLE B of this Standard, in order to maintain existing registrations or to obtain new product registrations.

3. Available data do not indicate that any of the criteria cited in 40 CFR 162.11 (b) have been equalled or

exceeded at this time. However, gaps in the data base preclude the completion of the Agency's risk assessment for naled.

4. Although the Agency is unable to complete a tolerance reassessment for naled because of a number of residue chemistry and toxicology data gaps, the Agency has concluded, based on available data, that no changes in present tolerances are necessary at this time. The Agency has also considered the residues of inorganic bromide, resulting from the use of naled on crops and in meat, milk, poultry and eggs, and does not anticipate these residues to be of toxicological concern, and no additional residue data on inorganic bromides are needed. However, the Agency is concerned about organic brominated metabolites of naled and its impurities. Accordingly, additional data on this organic bromide in plants and animals are being requested.

D. REGULATORY RATIONALE

The Agency has determined that it should continue to allow the registration of products containing naled, after considering the following:

1. Acute animal toxicity data indicate that technical naled is in Toxicity Category I on the basis of eye irritation, and Toxicity Category II on the basis of acute oral and dermal effects. Technical naled has been assigned Toxicity Category I for acute inhalation effects, pending receipt and evaluation of

a valid acute inhalation study. Human hazard precautionary statements associated with Toxicity Category I and Toxicity Category II labeling [40 CFR 162.10 (h)(2)(i)] should minimize the acute hazards associated with these routes of exposure.

2. Dichlorvos (DDVP), a metabolite of naled was originally referred to the Rebuttable Presumption Against Registration (RPAR) process because scientific studies indicated that dichlorvos was mutagenic and might cause cancer, nerve damage and birth defects in laboratory animals. The RPAR Decision Document on Dichlorvos, was issued by the Agency on September 30, 1982. In this document the Agency evaluated the available data on dichlorvos in accordance with 40 CFR 162.11 (Criteria for Determination of Unreasonable Adverse Effects) and concluded that the existing evidence does not support the issuance of an RPAR for dichlorvos and consequently, that an RPAR for naled as a precursor of dichlorvos is also not warranted.

However, the Decision Document concluded that additional data on carcinogenicity and mutagenicity are needed to complete the risk assessment for dichlorvos. Because the data base was incomplete, DDVP was removed from the RPAR process and returned to the registration process. On March 23, 1983, the Agency issued a Data Call-in Notice under FIFRA Section 3(c)(2)(b), requesting data on potential mutagenic effects of dichlorvos be submitted by March 23, 1985. Additionally, the Agency will wait until the ongoing National Cancer Institute (NCI) dichlorvos bioassay on carcinogenicity is completed (currently

scheduled for completion in 1984) and evaluated prior to determining if additional data on the carcinogenicity of dichlorvos will be required. Since dichlorvos is a metabolite of naled, evaluation of these studies will be necessary for the completion of the naled risk assessment.

3. No other human toxicological hazards of concern to the Agency have been identified in studies reviewed for this Standard.

4. Based on residue chemistry and toxicological considerations, there is no evidence to suggest that the current tolerances are likely to expose the public to unreasonable adverse effects.

5. The Agency has, for the period 1970-1981 (primarily 1979-1981) received reports of 55 pesticide incidents involving naled, either as sole active ingredient or in combination with other active ingredients. Of these 55 incidents, 40 involved definite or possible human exposure. In at least 9 of these cases there was a physician's diagnosis of pesticide poisoning. In 26 incidents there was medical and/or emergency room treatment with only one additional case requiring hospitalization. No fatalities were reported.

It is not certain from the summary information provided in the Pesticide Incident Monitoring System (PIMS) report what products or types of products were involved in these exposures, or whether some incidents may have resulted from

deliberate misuse and/or carelessness, or whether labeling directions were disregarded.

There were 6 reported incidents involving children 5 years of age or younger. In each of these incidents there was possible oral exposure. In at least one of these incidents a physician's diagnosis of pesticide poisoning was made. Again, it is not certain what products or type of products were involved. These incidents occurred during a period when the Agency did not require child-resistant packaging. The requirement of child-resistant packaging for products with acute oral LD_{50} values of 1500 mg/kg or less, approved for residential application (40 CFR 162.16) should reduce potential risks of accidental exposure.

The absence of reported fatalities, taken in conjunction with the apparent adequacy of medical and/or emergency room treatment in the vast majority of reported cases (only one reported case involving hospitalization) suggests an acceptably low level of risk associated with incidental or accidental exposure to naled products.

6. Naled degrades fairly rapidly with half-lifes of $\leq$ 8 hours in soils and $\leq$ 25 hours in aqueous solutions. Dichlorvos is also rapidly degraded in soil with half-lifes of 2.3 - 8.0 hours. Naled exhibits low to intermediate mobility in soils, whereas dichlorovos is intermediately mobile to mobile. Limited data indicate that the rapid dissipation and relatively low mobility of naled and inter-

mediate mobility of dichlorvos in soil will mitigate contamination of ground water.

7. Based on studies available to assess hazards to wildlife and aquatic organisms, naled is characterized as very highly toxic to bees and aquatic invertebrates. It is moderately to highly toxic to fish and slightly toxic to upland game birds and waterfowl. Insufficient data are available to assess the toxicity of naled to estuarine and marine organisms. Label precautionary statements required by this Standard should reduce the hazard to fish and other wildlife. After data gaps are filled, the potential hazards to terrestrial and aquatic species will be better defined and additional labeling requirements may be imposed.

8. Data are requested by the Agency to address organic bromide residues which may result from naled uses and are of human toxicological concern. Additional data may be requested if these residues are found to be significant.

9. The wildlife risk assessment indicates that naled residues on treated feed would not become hazardous to birds unless sixteen (16) pounds active ingredient per acre or greater were applied. Since the maximum registered application rate is four (4) pounds active ingredient per acre the warning "Birds feeding on treated areas may be killed" is inappropriate and should be deleted from all naled product labels.

10. Under FIFRA, the Agency cannot cancel or withhold registration simply because data are missing or inadequate [see FIFRA Sections 3(c)(2)(B) and 3(c)(7)]. Rather, issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registration(s) of naled.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To be covered by this Standard, products must contain naled as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section F of this document.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described herein. These include making a commitment to fill data gaps on a schedule specified by the Agency. Applicants for registration under this Standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be covered under this Standard, manufacturing-use products must contain naled as the sole active ingredient. Each MP

formulation proposed for registration must be fully described and include an appropriate certification of limits for all contaminates and impurities, and carry-over starting materials and/or intermediates above the level of 0.1% in the technical product.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade products and MPs containing naled for any acute toxicity category, provided that the labeling of those products bears appropriate precautionary statements.

3. Use Patterns

To be registered under this Standard manufacturing-use products containing naled may be labeled for formulation only into end-use products for:

° Terrestrial, food uses on: alfalfa (forage, seed), almonds, beans (dry, succulent), broccoli, Brussels sprouts, cabbage, cantaloupes, cauliflower, celery, chard (including Swiss), collards, cotton, cucumbers, eggplants, grapefruit, grapes, honeydew melons, hops, kale, lemons, lettuce, muskmelons, oranges, pastures (forage grasses and legumes)(including those for livestock and dairy cattle), peaches, peas (succulent), peppers, pumpkins, rangeland, safflower (seed), soybeans (beans: dry and succulent), spinach, squash (winter,

summer), strawberries, sugar beets, tangerines, tomatoes, turnips, turnip greens, walnuts, and watermelons.

° Terrestrial, non-food uses on: athletic fields, camp sites, cull piles, dwellings (including campers, hotels, motels, tourist courts, patios, and yards), fence rows, municipalities, ornamental conifers (including arborvitae, Douglas fir, hemlock, juniper, pine and spruce), ornamental deciduous trees (including ash, birch, black walnut, box-elder, crabapple, dogwood, elm, evergreen pear, flowering plum, flowering/ornamental quince, locust, magnolia, maple, oak, sycamore, walnut, and willow), ornamental grasses (including dichondra), ornamental herbaceous plants (including aster, Canterbury bells, carnations, dahlias, daisies, gladiolus, iris, marigold, nursery stock, stock, and zinnia), ornamental lawns, ornamental plants (including nursery stock), ornamental turf, ornamental woody shrubs (including aucaba, azalea, hibiscus, holly, juniper, nursery stock, pittosporum, privet and snowball), residential areas, roses (including nursery stock), sewage plants, swimming pool areas, theaters (open air), and tobacco.

° Aquatic, food uses on: rice.

° Aquatic, non-food uses on: marinas, swamps, swimming pool areas, and tidal marshes.

° Greenhouse, food uses on: vegetable crops (including cucumbers, mushrooms, and tomatoes).

° Greenhouse, non-food uses on: ornamental plants (including carnations, chrysanthemum, poinsettias, roses, and snapdragons).

° Forestry uses on: forest trees - conifers (including arborvitae, Douglas fir, fir, hemlock, juniper, pine and spruce), forest trees - deciduous (including ash, birch, black walnut, boxelder, dogwood, elm, locust, magnolia, maple, oak, sycamore, walnut, and willow), and woodlands.

° Domestic, outdoor uses on: dog houses, kennels, and dwellings (including campers, hotels, motels, tourist courts, patios and yards).

° Indoor uses on: animal buildings (for other than dairy cattle, poultry and pets)(including barns, feeding areas, shelters, and stables)(including cattle, goats, hogs, horses, and sheep), animal hospitals (for pets and other animals), calf barns, canneries, cats, cider mills, corrals, dairy barns (including milk rooms, equipment, and barnyards), dogs, dog houses, domestic dwellings (including campers, hotels, motels and tourist courts), drive-ins, factories, feedlots, garbage containers, garbage dumps, kennels (dog), livestock feeding areas, loading docks, meat packing establishments, pens, poultry droppings,

poultry houses (including equipment and yards)(including those for chickens, pheasants,and turkeys), poultry packing/processing plants, restaurants, warehouses, and wineries.

G. REQUIRED LABELING

All manufacturing-use products containing naled must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specified information regarding label requirements.

1. Use Pattern Statements

The ingredients statement for MPs must list the active ingredient as:

Naled, (1,2-dibromo-2,2-dichloroethyl dimethyl phosphate) . . . . . _ %.

In addition, all MPs must state that they are intended only for formulation into end-use products for any of the use patterns listed above. They must specify specific sites listed in Use Patterns in Section F.3. A limiting factor will be the data that supports these use patterns. No use may be included on the label, or labeling, where the registrant fails to agree to comply with the data requirements in either TABLE A for that use pattern, or TABLE B.

2. Precautionary Statements

Labels for all MP products containing naled must bear statements reflecting the acute human toxicity of the compound. Naled is in Toxicity Category I on the basis of eye irritation effects and Category II on the basis of acute oral and acute dermal toxicity or effects. The Agency has no valid acute inhalation or dermal sensitization data for naled. The required precautionary statements associated with Toxicity Category I and II are specified in 40 CFR §162.10.

The following environmental hazard statement must appear on the manufacturing-use product labels:

"This product is toxic to fish, aquatic invertebrates, and wildlife. Do not discharge into lakes, streams, ponds or public water unless in accordance with NPDES permit. For guidance contact your regional office of the Environmental Protection Agency."

Labeling changes to end-use products (EPs) are not required by this Standard, however, based on data reviewed by the Agency the following statements will be required for EPs under the Agency's Label Improvement Program.

°"This pesticide is toxic to fish, aquatic invertebrates, and wildlife. Do not apply directly to water or wetlands. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes."

- "This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area."

The following "General Warnings and Limitations" statements must appear on end-use product labels which bear directions for aquatic use on food or feed crops:

- "Do not use with highly alkaline materials such as lime or bordeaux mixture. Shrimp and crabs may also be killed at application rates recommended. Do not apply to tidal or marsh waters which are important shrimp producing areas."

The term "Birds feeding on treated areas may be killed" is inappropriate and should be deleted from all labels (reference D. Regulatory Rationale, 9).

PR Notice 83-2, dated March 29, 1983, sets forth current Agency policy on required label changes for reentry and farmworker safety. A reentry interval of 24 hours for the use of naled on crops is required. The Agency reserves the right to revise this reentry interval after receipt and review of the data required in TABLE A and TABLE B of this Standard.

The Agency may impose additional label requirements after the receipt and review of the data to be submitted under this Standard.

H. TOLERANCE REASSESSMENT

A summary of the tolerances for combined residues of naled and 2,2-dichlorovinyl dimethyl phosphate (DDVP) in or on raw agricultural commodities resulting from the application of naled formulations to growing crops, livestock and poultry (40 CFR 180.215, July 1981) is presented in Table I at the end of this section.

Canadian and Mexican tolerances are presented for comparison; it is not known whether these tolerances are for combined residues of naled and DDVP or for residues of naled alone. No international maximum residue limits (MRLs) have presently been established by the Codex Alimentarius Commission.

United States tolerances are identical with those of Canada and Mexico in all cases except peas and peppers, for which the U.S. and Canadian tolerances are 0.5 ppm and Mexican tolerances are 1 ppm (Table I). It must be noted that the commodities are defined differently by the respective countries in these two cases (see footnotes b and c in Table I). As previously mentioned, it is not known whether Canadian or Mexican tolerances are expressed in terms of combined residues of naled and DDVP (as U.S. tolerances are) or in terms of naled alone. Based on the above, as well as the absence of Codex MRLs for naled residues, compatibilities of international tolerances cannot be fully assessed at this time.

The components of the residue from the metabolism in plants which are of concern are naled and DDVP, and to a lesser extent, organic bromide. Additional data on the residues of organic bromide are being requested. Tolerances exist for combined residues of naled and DDVP (expressed as naled) and should continue to reflect the concern for these two components.

The components of the residue from the metabolism in animals which are of concern are the same as those in or on plants. However, data on the metabolism of naled in poultry are missing and this constitutes a data gap.

The Theoretical Maximum Residue Contribution (TMRC) is 1.1021 mg/day as naled, assuming a 1.5 kg diet, based on the tolerances and food factors for all of the commodities for which U.S. tolerances are established. No Acceptable Daily Intake (ADI) or Maximum Permissible Intake (MPI) figures have been established, due to the absence of acceptable toxicological data for naled. Reassessment of the established naled tolerances must await receipt and evaluation of the required data as set forth in TABLE A and TABLE B.

The tolerances for combined residues of naled and DDVP are supported for almonds (hulls and nuts), rice grain and forage, safflower seed , sugar beet roots and tops, and fat, meat and meat byproducts of cattle, goats, hogs, horses and sheep, and milk. No additional data are required for walnut meats because the residues in the consumed portion are expected to be mininal.

Tolerances are partially supported (for some uses) for forage legumes (alfalfa), grapes, grass forage, lettuce, summer squash, and tomatoes.

Additional data are required to support the tolerances for beans (dry and succulent), broccoli, Brussels sprouts, cabbage, cauliflower, celery, collards, cottonseed, cucumbers, eggplant, eggs, grapefruit, hops, kale, lemons, melons, mushrooms, oranges, pea forage, peaches, peas, peppers, poultry (fat, meat, meat by-products), pumpkins, soybean forage, spinach, strawberries, Swiss chard, tangerines, turnip tops, and winter squash.

Data are required on residues in the processed products of: citrus (any member fruit), cottonseed, grapes, hops, rice, and tomatoes. Data are also needed for turnip roots. A tolerance must be established for this commodity.

TABLE I. SUMMARY OF PRESENT TOLERANCES FOR NALED

Commodity	Tolerances (ppm) United States	Canada	Mexico
Almonds (hulls, nuts)	0.5	--	--
Beans (dry, succulent)	0.5	0.5	0.5
Broccoli	1.0	1.0	1.0
Brussels sprouts	1.0	1.0	--
Cabbage	1.0	1.0	--
Cattle (fat, meat, meat by-products)	0.05	--	--
Cauliflower	1.0	1.0	--
Celery	3.0	--	3.0
Citrus fruits [a/]	3.0	3.0	3.0
Collards	3.0	--	--
Cottonseed	0.5	--	0.5
Cucumbers	0.5	0.5	0.5
Eggplant	0.5	0.5	0.5
Eggs	0.05	--	--
Goats (fat, meat, meat by-products)	0.05	--	--
Grapes	0.5	--	0.5
Grasses, forage	10.0	--	--
Hogs (fat, meat, meat by-products)	0.05	--	--
Hops	0.5	--	--
Horses (fat, meat, meat by-products)	0.05	--	--

TABLE I (Continued)

Commodity	Tolerances (ppm) United States	Canada	Mexico
Kale	3.0	--	--
Legumes, forage	10.0	--	--
Lettuce	1.0	1.0	1.0
Melons	0.5	0.5	0.5
Milk	0.05	--	--
Mushrooms	0.5	--	--
Peaches	0.5	--	0.5
Peas [b/]	0.5	0.5	1.0
Pecans	--	--	0.5
Peppers [c/]	0.5	0.5	1.0
Poultry (fat, meat, meat by-products)	0.05	--	--
Pumpkins	0.5	0.5	--
Rice	0.5	0.5	0.5
Safflower seed	0.5	--	--
Sheep (fat, meat, meat by-products)	0.05	--	--
Soybeans	--	0.5	0.5
Spinach	3.0	3.0	3.0
Squash (summer, winter)	0.5	0.5	0.5
Strawberries	1.0	1.0	1.0

TABLE I (Continued)

Commodity	Tolerances		
	United States	Canada	Mexico
Sugar beets (roots, tops)	0.5	--	--
Swiss chard	3.0	3.0	--
Tomatoes	0.5	0.5	0.5
Turnips, tops	3.0	3.0	--
Walnuts	0.5	0.5	--
All other raw agricultural commodities except those listed d/	0.5	0.5	--

a/ United States tolerances are for grapefruit, lemons and tangerines; Canadian and Mexican tolerances are for all citrus fruits.

b/ United States tolerance is for succulent peas only; Canadian and Mexican tolerances are for all peas.

c/ The Mexican tolerance is for chili peppers only; the United States and Canadian tolerances are for all peppers.

d/ To account for area pest (fly and mosquito) control.

III. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix III-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data 1/Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Section IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix III-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix III-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

IV. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This section applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix IV-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED 1/

Data Requirement	Composition 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 3/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 4/
§158.120 Product Chemistry (continued)				
63-3 - Physical State	TGAI	Yes	00074790 G5092040	No
63-4 - Odor	TGAI	Yes	00074790 G5092040	No
63-5 - Melting Point	TGAI	Yes	G5092040	No
63-6 - Boiling Point	TGAI	Yes	00074653; 00074724* 00074790; G5092040	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Partial	00074653; 00074724* 00074790; G5092040	Yes 8/

*Data submitted by Chevron Chemical Company. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED 1/

Data Requirement	Composition 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 3/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 4/
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	TGAI OR PAI	Yes	00074653 00074790 GS092040	No
63- 9 - Vapor Pressure	TGAI OR PAI	Yes	00074653 00074790 GS092040	No
63-10 - Dissociation constant	TGAI OR PAI	No	-	Yes
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes
63-12 - pH	TGAI	No	-	Yes
63-13 - Stability	TGAI	Yes	00074653 00074724 00074790	No
Other Requirements:				
64- 1 - Submittal of samples	Choice	-	-	No 9/

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

§158.120 Product Chemistry
(continued)

1/ Naled 90% technical is the only technical product. The cited data may be used to satisfy the requirements for technical naled manufactured by the process submitted by the Chevron Chemical Co. (00074653 and 00074791) containing 90% naled (or similar percentages accepted on a product by product basis).
2/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
3/ All data cited were submitted by the Chevron Chemical Company.
4/ Data must be submitted no later than June 1986.
5/ Adequate data has been submitted by Chevron Chemical Company. Other producers must address these data requirements.
6/ The analytical methods used were inadequately described. Identification and quantification of impurities present at >0.1% (W/W) is required.
7/ There was a discrepancy of the limits. An update of the technical naled limits and quality control method (including validation data); adequate sampling (five or more production batches); and limit certification are required
8/ The data are conflicting. Clarification of the specific gravity of technical naled is required.
9/ May be required on a case-by-case basis.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partial	00074836 GS092090* 00074654 00074647	Yes 3/,4/
- Livestock	PAIRA and plant metabolites	Partial	00074844 00059386 GS092091* GS092092*	Yes 3/
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Partial	00074721; 00074806* 00074647; 00073820 00074725	Yes 4/
- Animal residues	TGAI and metabolites	Yes	GS092026 00073821*	No
171-4 - Storage Stability Data	PAI	No	-	Yes 5/

*Data submitted by Chevron Chemical Company. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use 6/				
- Root and Tuber Vegetable Group				
° Sugar Beet Roots	TEP	Yes	00074836; 00073821*; 00073815*; 00073819*	No
° Turnip Roots	TEP	No	-	Yes 7/
- Leaves of Root and Tuber Vegetables (Human Food or Animal Feed) Group 8/				
° Sugar Beet Tops	TEP	Yes	00074836; 00073821*; 00073815*; 00073819*	No 9/
° Turnip Tops	TEP	Partial	00073820	Yes 10/
- Leafy Vegetables Group (Except Brassica)				
° Celery	TEP	Partial	00074836; 00073821*; 00074722	Yes 11/
° Lettuce	TEP	Partial	00073820; 00074807	Yes 12/
° Spinach	TEP	Partial	00073820; 00074722	Yes 13/
° Swiss Chard	TEP	Partial	00074836	Yes 13/

*Data submitted by Chevron Chemical Company. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
- Brassica (Cole) Leafy Vegetable Group				
° Broccoli	TEP	Partial	00074836; 00073820	Yes 14/
° Brussels Sprouts	TEP	No	-	Yes 15/
° Cabbage	TEP	Partial	00074836	Yes 14/
° Cauliflower	TEP	Partial	00073820	Yes 14/
° Collards	TEP	Partial	00073821*	Yes 14/
° Kale	TEP	Partial	00073821*	Yes 14/
- Legume Vegetables (Succulent and Dried) Group				
° Beans	TEP	Partial	00074836; 00073846*; 00073820; 00074699; 00073821; 00074729	Yes 16/
° Peas	TEP	Partial	00073846*	Yes 17/
° Soybeans	TEP	Partial	00073821*; 00073846*	Yes 18/

*Data submitted by Chevron Chemical Company. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
- Foliage of Legume Vegetables Group				
° Bean Foliage	TEP	Partial	00074836; 00073820; 00073821*; 00073846*; 00074699; 00074729	Yes 19/
° Pea Foliage	TEP	Partial	00073846*	Yes 20/
° Soybean Foliage	TEP	Partial	00073821*; 00073846*	Yes 21/
- Fruiting Vegetables (Except Cucurbit) Group				
° Eggplants	TEP	No	-	Yes 22/
° Peppers	TEP	Partial	00074836*; 00073820	Yes 23/
° Tomatoes	TEP	Partial	00074836; 00073820; 00075668	Yes 24/
- Fruiting Vegetables (Cucurbit) Group				
° Cucumbers	TEP	Partial	00073820; 00075668	Yes 25/
° Melons	TEP	Partial	00073820	Yes 26/
° Pumpkins	TEP	No	-	Yes 27/
° Summer Squash	TEP	Partial	00073820	Yes 28/
° Winter Squash	TEP	No	-	Yes

*Data submitted by Chevron Chemical Company. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2
§158.125 Residue Chemistry (continued)				
- Citrus Fruits (Citrus Spp., Fortunella Spp.) Group				
° Grapefruit	TEP	No	-	Yes
° Lemons	TEP	Partial	00073820	Yes 29/
° Oranges	TEP	Partial	00073820; 00074807	Yes 30/
° Tangerines	TEP	No	-	Yes
- Stone Fruits Group				
° Peaches	TEP	Partial	00074836*; 00073821*	Yes 31/
- Small Fruits and Berries Group				
° Grapes	TEP	Partial	00074836; 00073821*; 00074728; 00073817*	Yes 32/
° Strawberries	TEP	Partial	00073820	Yes 33/
- Cereal Grains Group				
° Rice Grain	TEP	Partial	00074723; 00073820;	Yes 34/

*Data submitted by Chevron Chemical Company. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2
§158.125 Residue Chemistry (continued)				
- Forage, Fodder, and Straw of Cereal Grains Group				
° Rice Forage	TEP	Yes	00074723 00073820	No 35/
- Grass, Forage, Fodder and Hay Group				
° Grass Forage (Pasture and Range)	TEP	Partial	00073816*	Yes 36/
- Non-Grass Animal Feeds (Forage, Fodder, Straw, and Hay) Group				
° Alfalfa	TEP	Partial	00074836; 00073821*; 00073818*; 00072816	Yes 37/
- Tree Nuts Group 38/				
° Almonds	TEP	Yes	00073830	No 39/
° Walnuts	TEP	Yes	00073821*	No

*Data submitted by Chevron Chemical Company. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2
§158.125 Residue Chemistry (continued)				
- Miscellaneous				
° Cottonseed	TEP	Partial	00074700; 00073821*; 00074845*	Yes 40/
° Hops	TEP	Partial	00073846*	Yes 41/
° Mushrooms	TEP	Partial	GS092093	Yes 42/
° Safflower Seed	TEP	Yes	00073846*; 00074845*	No 43/
- All Other Agricultural Commodities	TEP	No	-	No 44/
- Food Producing Animals				
° Meat and milk	EP, TGAI or plant metabolites	Yes	GS092094 GS092092* GS092095* 00073821* GS092026	No 45/
° Poultry and eggs	EP, TGAI or plant metabolites	Partial	GS092096 00074692*	Yes 46/,47/

*Data submitted by Chevron Chemical Company. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

§158.125 Residue Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.
2/ Data must be submitted no later than June 1986.
3/ Data are needed on the identity and amount (if any) in plants and animals of organic brominated components of the residue derived from naled itself or from its bromine-containing impurities. A protocol for this study must be submitted and approved by the Agency, prior to initiation of the study. The protocol must include a scheme for tracking organic-brominated residues.
4/ Methodology and data on residues of naled and DDVP determined separately for two representative crops such as lettuce and rice grain are needed.
5/ Some residue storage data is required to indicate a potential for the loss of residues between sampling and analysis.
6/ The following agricultural commodities are arranged in order of crop groups in accordance with Draft Proposed 40 CFR 180.34(f) [see FR 47(93)20635(5-13-82)]. Satisfaction of the crop group requirements for a given group would allow the establishlment of a tolerance for all members of that group. To satisfy the requirements, the use patterns must be similar for all members of the crop group and maximum residues (tolerances) generally must not vary by more than a factor of five. Residue data for all of the representative commodities, or suitable substitutes, must be presented in order to establish a group tolerance; these representative crops are listed under the crop group sections which follow.
7/ No tolerances exists for turnip roots, yet residues are to be expected from the use on naled on turnips. These residues need to be covered by either a crop group tolerance (as previously indicated) or an individual tolerance. The lack of residue data on turnip roots constitutes a data gap for an individual tolerance, should one be requested.
8/ Data are available for both of the two representative commodities (sugar beet tops and turnip tops) needed to satisfy the requirements for this crop group. Based on the available data, however, a group tolerance cannot be established for the following reasons: 1) Residue data for turnip tops do not support the established tolerance, 2) Naled uses for turnips and sugar beets are substantially different in terms of the rates and formulations applied for, and 3) The tolerances for sugar beet tops (0.5 ppm) and turnip tops (3.0 ppm) differ by ;more than a factor of five.
9/ The available data support the tolerance for combined residues of naled and DDVP in or on sugar beet tops from the established use, and even under exaggerated rates of application. The restriction against feeding sugar beet tops to livestock appears unnecessary.
10/ Data are needed which reflect aerial and ground applications of the 4 or 6% Dusts (D) and 7.2 lb/gal Emulsifiable Concentrates (ECs) according to the use pattern. This will include five or more applications per season at the highest recommended rates.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

§158.125 Residue Chemistry
(continued)

11/ Data are needed which reflect the following: 1) Five or more ground applications of the 7.2 lb/gal EC at 1.35 lb ai/A, 2) Five or more aerial applications of the 4 or 6% D at 2.0 lb ai/A, and 3) Five or more ground applications of the 4 or 6% D at 2.0 lb ai/A.

12/ The available data support the established tolerance for head lettuce after applications of the 7.2 lb/gal EC. Additional data are required which reflect both aerial and ground applications of either the 4 or 6% D; at least three applications at 2.0 lb ai/A must be made. All of the above data are required for leaf lettuce as well (including data for the 7.2 lb/gal EC). These data are to include at least one study to show residues in head lettuce, with and without wrapper leaves.

13/ Data are needed which reflect aerial and ground applications of the 4 or 6% dusts and the 7.2 lb/gal EC according to the use pattern. This will include five or more applications per season at the highest recommended rates.

14/ Data are needed which reflect five or more seasonal applications, with aerial and ground equipment, of the 4 or 6% D at 2.01b ai/A and of the 7.2 lb/gal EC at 1.8 lb ai/A.

15/ No residue data for Brussels sprouts are available for review; the tolerance can be supported by grouping with other crops whose tolerances are supported, or by residue data for the individual tolerance.

16/ Data are required which reflect three or more applications of the 7.2 lb/gal EC and the 4 or 6% D formulations during the fruiting period with aerial and ground equipment.

17/ Data are required which reflect at least three applications of the 4% D and the 7.2 lb/gal EC at the maximum rates during the fruiting period. Both aerial and ground equipment must be used. Dried, succulent, and edible-pod types must be included.

18/ Data are needed which reflect at least five aerial and ground applications of the 7.2 lb/gal EC at 1.35 lb ai/A; three of these treatments must be made during the fruiting period. Data are also needed to determine the residues in processed soybean products (crude and refined oil, hulls, meal, and soapstock) to establish the necessity of food additive tolerances for residues in these products.

19/ Data are required which reflect three or more applications of the 7.2 lb/gal EC and the 4 or 6% D formulations with aerial and ground equipment. The restriction against feeding bean forage to livestock appears unnecessary.

20/ Data are required which reflect at least three applications of the 4% D and 7.2 lb/gal EC at the maximum rates be made during the fruiting period using aerial and ground equipment.

21/ Data are needed which reflect at least five aerial and ground applications of the 7.2 lb/gal EC at 1.35 lb ai/A for forage; three of these treatments must be made during the fruiting period for residue studies on pods and vines.

22/ No residue data for eggplant are available for review; the tolerance can be supported by grouping with other fruiting vegetables (except cucurbits) whose tolerances are supported, or by residue data for the individual tolerance.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

§158.125 Residue Chemistry
(continued)

23/ Data are needed which reflect five aerial and ground applications of the 4% D and the 7.2 lb/gal EC; at least three of these applications must be made during the fruiting period.

24/ The available data support the established tolerance for tomato fruit following ground applications of the 7.2 lb/gal EC. Data are still needed which reflect: 1) Five aerial applications of the 7.2 lb/gal EC at 0.9 lb ai/A (at least three applications must be made during the fruiting period), 2) Five aerial and ground applications of the 4% D at 2.0 lb ai/A (at least three applications must be made during thr fruiting period, 3) Five foliar greenhouse sprays with the 7.2 lb/gal EC at 0.9 lb ai/100 gal (at least three applications must be made during the fruiting period), 4) Ten greenhouse fumigations with the RTU and 7.2 lb/gal EC at 16 fl oz of product/50,000 cu ft, and 0.28 lb ai/50,000 cu ft, respectively, (at least five applications must be made during the fruiting period), and 5) Residues in processed tomato products (ketchup, paste, and wet and dry pomace).

25/ Data are needed which reflect the following: 1) Five aerial and ground applications of the 4% D at 2.0 lb ai/A (at least three applications must be made during the fruiting period), 2) Five aerial and ground applications of the 7.2 lb/gal EC at 1.35 lb ai/A (at least three applications must be made during the fruiting period), and 3) Ten greenhouse fumigations using the 7.2 lb/gal EC and 10% RTU at 0.28 lb ai/50,000 cu ft and 16 oz product/50,000 cu ft, respectively (at least five applications must be made during the fruiting period).

26/ Data are needed which reflect the following: Five aerial and ground applications of the 4% D at 2.0 lb ai/A (at least three applications must be made during the fruiting period).

27/ Data are needed which reflect the following: 1) Five aerial and ground applications of the 4% D at 2.0 lb ai/A (at least three applications must be made during the fruiting period), and 2) Five aerial and ground applications of the 7.2 lb/gal EC at 1.35 lb ai/A (at least three applications must be made during the fruiting period). The available data on rice straw are applicable to other grain straws and indicate that these contribute substantially to the bromide ion content of the animal diet.

28/ The available data support the established tolerance for summer squash treated with ground applications of the 7.2 lb/gal EC. Additional data are required which reflect the following: 1) Five aerial applications of the 7.2 lb/gal EC at 1.35 lb ai/A (three or more applications must be made during the fruiting period), and 2) Five aerial and ground applications of the 4% D at 2.0 lb ai/A (three or more applications must be made during the fruiting period).

29/ Data are needed which reflect 10 aerial and ground applications of the 4% D and 7.2 lb/gal EC at 4.0 and 1.8 lb ai/A, respectively; five or more of these applications must be made during the fruiting period.

30/ Data are needed which reflect 10 aerial and ground applications of the 4% D and 7.2 lb/gal EC at 4.0 and 1.8 lb ai/A, respectively; five or more of these applications must be made during the fruiting period. Data is also needed on processed products, cold pressed oil, peel, dehydrated pulp and molasses (fractionation study).

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

§158.125 Residue Chemistry
(continued)

31/ Data are required which include the following; 1) Ten ground applications of the 7.2 lb/gal EC at 0.68 lb ai/100 gal sprayed to the point of runoff, 2) Ten aerial and ground applications of the 4% D at 3.2 lb ai/A.

32/ The available data support the established tolerance for grapes based on residues resulting from ground application of the 7.2 lb/gal EC. Additional dat are required which reflect 10 aerial and ground applications of the 4% D at 2.0 lb ai/A. Also, data pertaining to naled residues in the following grape products (juice, wet and dehydrated pomace, raisins, and raisin waste) are needed to determine if food additive tolerances should be established for these products.

33/ Data are required which reflect five aerial and ground applications of the 4 or 6% D at 2.0 lb ai/A and the 7.2 lb/gal EC at 0.9 lb ai/A.

34/ The available data support the established tolerance for residues of naled and DDVP in or on rice resulting from the use of the 7.2 lb/gal EC. Data are required for rice products (hulls and milled products and by-products) to determine if feed additive tolerances need be established for these products.

35/ The available data support the established tolerance for residues of naled and DDVP in or on rice forage resulting from the use of the 7.2 lb/gal EC.

36/ The available data support the established tolerance on pasture and range grasses for foliar ground application of the EC and SC/L formulations. Data are required, however, which reflect five aerial applications of the EC and one of the SC/L formulations at 0.9 and 0.75 lb ai/A, respectively. Also, residue data are required which reflect five aerial and ground applications of the 4% D at 0.4 lb ai/A. In addition, residue data for grass hay are needed to determine if a separate, or increased, tolerance should be established for this dehydrated product.

37/ The available data support the established tolerance for alfalfa forage following treatment with the EC and SC/L formulations. Additional data are required which reflect five aerial and ground applications of the 4% D. Residue data for alfalfa hay are also needed to determine if a separate, or increased, tolerance should be established for this dehydrated product.

38/ A group tolerance may not be established at this time because the almond and walnut uses are distinctly different, and because additional data are required for pecans.

39/ The available data support the established tolerance for almond hulls and nuts following a dormant application. In addition, the data indicate that three foliar applications at 3.0-6.0 lb ai/A do not result in tolerance-exceeding residues in or on almond hulls and meats 28 days after the final treatment. The use pattern could thus be expanded to include foliar applications of the 7.2 lb/gal EC if such a need is anticipated.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

§158.125 Residue Chemistry
(continued)

40/ Data are required for cottonseed which reflect five aerial and ground applications of the 4% D and 7.2 lb/gal EC at 1.4 and 0.9 lb ai/A, respectively. If residues are, in fact, present in undelinted seed, then additonal residue data (reflecting the above doses) for cottonseed hulls, meal, refined oil, and soapstock are required to determine if food additive tolerances should be established for these proccessed products.

41/ Data are required on hops which reflect five aerial and ground applications of the 4% D and 7.2 lb/gal EC at 1.0 and 0.9 lb ai/A, respectively. Also, data are required concerning residues in dried spent hops.

42/ Data from the following uses are needed: 1) 20 applications of the 7.2 lb/gal EC used as a RTU at 6.75 oz ai/50,000 cu ft, and 2) 20 applications of the 10% RTU at 5 fl oz/50,000 cu ft.

43/ The available data support the established tolerance for combined residues of naled and DDVP in or on safflower seed and indicate that food additive tolerances need not be established for safflower meal and oil. This data cannot be translated to other oilseeds because their fractions inlude hulls and soapstock.

44/ A tolerance of 0.5 ppm is established for combined residues on naled and DDVP in or on all raw agricultural commodities, except those otherwise listed in 40 CFR 180.125 (July 1981), from use of naled formulations for area pest (fly and mosquito) control. The recommended rates are consistently lower (frequently 0.02-0.25 lb ai/A) for area pest uses than for crop pest uses (usually 0.68-4.0 lb ai/A). Although it is a major use on naled formulations, area pest usage will result in intermittent and variable exposure of a given commodity to naled residues. For these reasons, the submission of data to support this extensive tolerance is not required. All commodities included in this tolerance will, of course, be subject to enforcement of this tolerance.

45/ The available data support the established tolerances for combined residues of naled and DDVP from dietary sources in the meat and milk of cattle. The data are considered supportive of the tolerances for residues in the meat and milk of otherr animals (goats, hogs, horses and sheep) as well. The contribution of combined residues on naled and DDVP to meat and milk from the use of naled at its reduced rates on or around livestock is not expected to be significant in relation to the levels which result from dietary sources.

46/ Residue data are needed on eggs and poultry resulting from 10 bird-spray treatments with either the 3.6 or 7.2 lb/gal EC at 0.45 lb ai/20 gal.

47/ Data submitted to the Agency was conducted by Industrial Bio-Test Laboratories (IBT) and has been determined to be invalid.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,D, E,F,G,H	No	-	Yes
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B,C,G	No	-	Yes
161-3 - On soil	TGAI or PAIRA	A,G	No	-	Yes
161-4 - In Air	TGAI or PAIRA	A,C,E,F	No	-	Yes
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,D,E, F,H	Partial 4/	00074759*	Yes
162-2 - Anaerobic Soil	TGAI or PAIRA	A,G	No 5/	-	Yes
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C,D,G	No	-	Yes
162-4 - Aerobic Aquatic	TGAI or PAIRA	C,D	Partial 6/	00074691* 00074885* 00074644**	Yes
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,D, E,F,G,H	Partial 7/	00064796*	Yes
163-2 - Volatility (Lab)	TEP	A,E,F	No	-	Yes
163-3 - Volatility (Field)	TEP	A,E,F 8/	No	-	Reserved 9/

*Data submitted by Chevron Chemical Company. These data may be compensable.
**Data submitted by National Chemsearch, Division of NCH Corp. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B,H	No	-	Yes
164-2 - Aquatic (Sediment)	TEP	C,D	Partial 10/	00074645*	Yes
164-3 - Forestry	TEP	G	No	-	Yes
164-4 - Combination and Tank Mixes	TEP		Not Applicable	-	-
164-5 - Soil, Long-term	TEP	A	Reserved 11/		
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	No	-	Yes
165-2 - Rotational Crops (Field)	TEP	A	No	-	Reserved 12/
165-3 - Irrigated Crops	TEP	C	No	-	Yes
165-4 - In Fish	TGAI or PAIRA	A,B,C, D,G	Yes	00074643*	No 13/
165-5 - In Aquatic Non-Target Organisms	TEP	D	Yes	00074643*	No

*Data submitted by National Chemsearch, Division of NCH Corp. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

§158.130 Environmental Fate
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than June 1986.
4/ Tests with specified purity of radiolabeled or technical material required (composition test material not given).
5/ Anerobic aquatic studies replace the anerobic soil studies.
6/ Half-life was given, but only on one metabolite (DDVP). No information was given on DDVP metabolism, nor on sediment. Data from the intended use area(s) is required.
7/ Aged leaching tests are required to identifiy metabolites and degradation rates. No absorption/desorption data were submitted, therefore all data are required.
8/ Label modifications for the greenhouse use may be necessary because of high volatility and toxicity (Category II) of the metabolite DDVP. A decision will be made after an additional aerobic soil metabolism study is submitted and evaluated.
9/ Data requirement depends on the results of the laboratory studies.
10/ Partial information obtained from sewage water; additional data required on dissipation from other aquatic impact areas.
11/ This study is required only if the aerobic soil metabolism study described in 162-1 demonstrates that for field and vegetable crop use, the total amount of pesticide, excluding bound residues in soil, is greater than 50% of the amount of pesticide initially applied at the time when a subsequent application would occur.
12/ Reserved pending results of 165-1.
13/ No data on the accumulation of naled in fish are required because 1) naled has a half life of less than 4 days in water, 2) naled has an octanol water partition coefficient of less than 1000, and 3) no detectable residues were found in fish samples.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A,B,C,D,E F,G,H,I	Yes	00049330 00074795 05016607 00065468	No
81-2 - Dermal LD_{50} - Rabbit	TGAI	A,B,C,D,E, F,G,H,I	Yes	00074829* 00074663 00049330	No
81-3 - Inhalation LC_{50} - Rat	TGAI	A,B,C,D,E, F,H,I	No	-	Yes
81-7 - Delayed Neurotoxicity - Hen	TGAI	A,B,C,D,E, F,G,H,I	Yes	00074656* 00074843	No
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,D,E,I	Yes	00074817 05016607 GS092097* 00074862	No
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,H,I	No	-	Yes
82-3 - 90-Day Dermal - Rabbit	TGAI		Reserved 4/	-	-
82-4 - 90-Day Inhalation - Rat	TGAI	E,F,I	No	-	Yes
82-5 - 90-Day Neurotoxicity- Hen/Mammal	TGAI		No	-	No 5/

*Data submitted by Chevron Chemical Company. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

§158.135 Toxicology
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than June 1986.
4/ Reserved pending results of 82-2 (21-day dermal).
5/ Not required since 81-7 (acute delayed neurotoxicity) does not show neurotoxicity.
6/ This study is to be completed by April 3, 1985, in accordance with the 3(c)(2)(B) Data Call-in Notice issued April 3, 1981.
7/ Data previously sbumitted to the Agency was conducted by Industrial Bio-Test Laboratories (IBT) and has been determined to be invalid.
8/ This study is to be completed by September 3, 1983, in accordance with the 3(c)(2)(B) Data Call-in Notice issued April 3, 1981 and a request for a 3-month extension.
9/ This data requirement is statisfied for bacterial testing only.
10/ Reserved pending results of subchronic and chronic testing.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A,B	No	-	Yes 4/
132-1 - Soil Dissipation	TEP	A,B	No	-	No 5/
133-3 - Dermal Exposure	TEP	A,B	No	-	No 5/
133-4 - Inhalation Exposure	TEP	A,B	No	-	No 5/

1/ Composition: TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than June 1986.
4/ Use California reentry interval of 24 hours for all crops, or submit foliar dissipation data to establish a decline curve.
5/ Only foliar dissipation data are required.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A,B,C,D,G	Yes	GS092099	No
71-2 - Avian Dietary LC_{50}	TGAI	A,B,C,D, E,F,G,H, I 4/	Yes	00028757	No
71-3 - Wild Mammal Toxicity	TGAI	A,B,C,D,G	No	-	No 5/
71-4 - Avian Reproduction	TGAI	A,B,C,D,G	No	-	No 5/
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B,C,D,G	No	-	No 5/
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A,B,C,D, E,F,G,H, I 4/	Yes	05003107 GS092101 GS092102	No
-do-	TEP	C,D,G	Partial	GS092101 GS092102 GS092017	Yes 6/

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms (continued)					
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,G,C,D, E,F,G,H, I 4/	Yes	GS092100	No
-do-	TEP	C,D,G	No	-	Yes 6/
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	C,D,G	Partially 7/	GS092104 00074684	Yes
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	C,D,G	Reserved 8/		
72-5 - Fish - Life-Cycle	TGAI	C,D,G	Reserved 9/		
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	C,D,G	Reserved 9/		
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	C,D,G	Reserved 9/		

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

§158.145 Wildlife and Aquatic Organisms
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than June 1986.
4/ Only one species is required for the E,F,H and I use patterns.
5/ This data is not normally required.
6/ In addition to the technical, data must be submitted on unique formulations that are formulated for use in aquatic sites.
7/ In addition to the technical, testing is required for establishing the acute toxicity of the technical pesticide to estuarine/marine invertebrates when the end-use product is expected to enter the estuarine or marine environment in significant concentrations because of its use or mobility patterns. In the case of naled, it is used for mosquito control in estuarine marshes and swamps. Studies will include 48 hour oyster embryo-larvae or 96 hour shell deposition, 96 hour juvenile shrimp and 96 hour estuarine finfish (spot or pinfish). The available studies do not satisfy any of the guideline requirements and do not provide an adequate basis for assessing naled. Since naled is very highly toxic to Daphnia, it is essential to conduct the appropriate tests on estuarine organisms.
8/ Reserved pending submission of appropriate environmental fate studies (e.g., hydrolysis) which are needed to determine the persistence of naled in the aquatic environment.
9/ Reserved pending submission of appropriate environmental fate studies (e.g., dissipation and hydrolysis studies) which are needed to determine if hazardous concentrations of naled will reach or accumulate in the aquatic environments when products are used as directed.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirements	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP		No	-	No 4/
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI		No	-	No 4/
122-1 - Vegetative Vigor	TGAI		No	-	No 4/
122-2 - Aquatic Plant Growth	TGAI		No	-	No 4/
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI		No	-	No 4/
123-1 - Vegetative Vigor	TGAI		No	-	No 4/
123-2 - Aquatic Plant Growth	TGAI		No	-	No 4/
TIER III					
124-1 - Terrestrial Field	TEP		No	-	No 4/
124-2 - Aquatic Field	TEP		No	-	No 4/

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than _____.

4/ These requirements are generally waived unless it is believed there is a phototoxicity problem.

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	A,B,G,H	Yes	00036935	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B,G,H	Yes	00060628 00037799 05000837	No
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	A 4/	Yes	00060628 05000837	No
141-4 - Honey bee subacute feeding study	TEP	A,B,G,H	Reserved 5/	-	-
141-5 - Field testing for pollinators	TEP	A,B,G,H	No	-	No 6/

TABLE A
GENERIC DATA REQUIREMENTS FOR NALED

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	-		Reserved 7/		
142-2 - Aquatic insect life-cycle study	-		Reserved 7/		
142-3 - Simulated or actual field testing for aquatic insects	-		Reserved 7/		
143-1 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES thru 143-3	-		Reserved 7/		

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than 6/86.
4/ Data required only for pesticides intended for foliar application to seed alfalfa.
5/ Reserved pending development of test methodology.
6/ May be required under the following conditions:
i) Data from the honey bee subacute feeding study (141-4) indicate adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.);
ii) Data from residual toxicity studies (141-2 and 141-3) indicate extended residual toxicity; or
iii Data derived from studies with organisms other than bees indicate properties of the pesticide beyond acute toxicity such as the ability to cause reproductive or chronic effects.
7/ Reserved pending decision as to whether data requirement should be established.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NALED 1/

Data Requirement	Composition 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 3/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 4/
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	MP	Yes	00074653 00074724 GS092040	No
61-2 - Statement of Composition	MP	Partial	00074653 00074791*	Yes 5/
61-3 - Discussion of Formation of Ingredients	MP	Partial	00065493; 00065494* 00074653; GS092040	Yes 6/
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	MP	Partial	00065493*; 00065494*; 00074655; 00074653	Yes 6/
62-2 - Certification of Limits	MP	Partial	00065493*; 00065494*; 00074653	Yes 7/
62-3 - Analytical Methods for Enforcement of Limits	MP	Partial	00065494*; 00074653 00074655; 00074724 00074846; G5092006	Yes 7/
Physical and Chemical Characteristics				
63-2 - Color	MP	Yes	00074790 G5092040	No

*Data submitted by Chevron Chemical Company. These data may be compensable.

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NALED

TABLE B

Data Requirement	Composition 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 3/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 4/
§158.120 Product Chemistry (continued)				
63-3 - Physical State	MP	Yes	00074790 G5092040	No
63-4 - Odor	MP	Yes	00074790 G5092040	No
63-7 - Density, Bulk Density, or Specific Gravity	MP	Partial	00074653; 00074724 00074790; G5092040	Yes 8/
63-12 - pH	MP	No	-	Yes
63-14 - Oxidizing or reducing action	MP	Yes	00074790	No
63-15 - Flammability	MP	Partial	00074790	Yes 9/
63-16 - Explodability	MP	Yes	00074790	No
63-17 - Storage Stability	MP	Yes	00074653	No
63-18 - Viscosity	MP	Yes	00074790 GS092040	No
63-19 - Miscibility	MP	Yes	00074790 GS092040	No
63-20 - Corrosion	MP	Yes	00074790 GS092040	No
Other Requirements:				
64- 1 - Submittal of samples	MP	-	-	No 10/

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NALED

§158.120 Product Chemistry
(continued)

1/ Naled 90% technical is the only manufacturing-use product.
The cited data may be used to satisfy the requirements for manufacturing-use naled manufactured by the process submitted by the Chevron Chemical Co. (00074653 and 00074791) containing 90% naled (or similar percentages accepted on a product by product basis).
2/ Composition: MP = Manufacturing-use product.
3/ All data cited were submitted by the Chevron Chemical Company.
4/ Data must be submitted no later than December 1983.
5/ Adequate data has been submitted by the Chevron Chemical Company. Other producers must address these data requirements.
6/ The analytical methods used were inadequately described. Identification and quantification of impurities present at >0.1% (W/W) is required.
7/ There was a discrepancy of the limits. An update of the manufacturing-use naled limits and quality control method (including validation data); adequate sampling (five or more production batches); and limit certification are required
8/ The data are conflicting. Clarification of the specific gravity of manufacturing-use naled is required.
9/ The data are unclear. Clarification of the flammability of the manufacturing-use naled is required.
10/ May be requested on a case-by-case basis.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NALED

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Yes	00049330 00074795 05016607 00065468	No
81-2 - Dermal LD_{50} - Rabbit	MP	Yes	00074829* 00074663 00049330	No
81-3 - Inhalation LC_{50} - Rat	MP	No	-	Yes
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	GS092002	No
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	GS092001 GS092098	No
81-6 - Dermal Sensitization - Guinea Pig	MP	No	-	Yes 3/

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than December 1983.
3/ Data submitted to the Agency was conducted by Industrial Bio-Test Laboratories (IBT) and has been determined to be invalid.

*Data submitted by Chevron Chemical Company. These data may be compensable.

V. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix V-1 and V-2], as indicated by the following paragraphs of this section of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

A. Label Contents

40 CFR §162.10 (Appendix V-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix V-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix V-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix V-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix V-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix V-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix V-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix V-1. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix V-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix V-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix V-1. [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

VI. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

William H. Miller
Phone No. (703) 557-2600
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

A. For each manufacturing-use product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix III-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix IV-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

B. For each affected product for which continued registration is desired, within 90 days from receipt of this document submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, Appendix III-2) with appropriate attachments.

C. You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has

shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE	
ACTIVE INGREDIENT	
NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

Appendix IV-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				

Appendix IV-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by: Citing MRID#	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Producls (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: Initiation of Reregistration Process for Manufacturing-Use Products and Certain End-Use Products Containing Naled as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this manufacturing-use standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the

steps you must take to maintain registration for your product(s). Products not brought into compliance with the Guidance Document as supplemented by subsequent information from EPA about compliance with certain data support requirements will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.

2. Fxplains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.

3. Sets out time-frames for submission of required data.

4. Explains how to revise labeling for maufacturing use products. (As the Guidance Document explains, labeling is not required at this time.)

5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that <u>if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended</u>.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

Mr. William H. Miller
Product Manager 16
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Telephone: 703/557-2600

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

Enclosure

ATTACHMENT A

PRODUCTS AFFECTED BY THIS
REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

ATTACHMENT B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING
THE ACTIVE INGREDIENT

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient and type of formulation, such as Manufacturing-Use Product (MP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).